Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1.-20. (Canceled)

21. (Previously Presented) An autoclavable composition of an aqueous injectable, terminally steam sterilized suspension in a vial sealed under nitrogen atmosphere, said suspension consisting essentially of particles of a water insoluble or poorly soluble biologically active substance with a volume weighted mean particle size of up to 3 μm, with not more than 3000 particles of a size of 10 μm or greater and not more than 300 particles of a size of 25 μm or greater, said particles surface stabilized with one or more phospholipid surface modifiers, and a pharmaceutically acceptable amount of a water soluble polyhydroxy thermoprotecting agent selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol and mixtures thereof, wherein the ratio of said active substance to said phospholipid surface modifier is from about 3:1 to about 5:1 and the amount of said phospholipid surface modifier is in the range from about 0.2% w/w to about 5.0% w/w, wherein said composition is devoid of surfactants that require during terminal steam sterilization elevation of their cloud point temperature by addition of a cloud point modifier, said composition being devoid of surfactant additives which coagulate on steam sterilization, and further wherein the volume weighted mean particle size of said particles is not increased more than two-fold during and after terminal steam sterilization.

22. (Previously Presented) An autoclavable composition of an injectable, non-flocculating, aqueous, terminally steam sterilized suspension under nitrogen in a sealed vial, said suspension consisting essentially of particles of a water insoluble or poorly soluble drug substance with a volume weighted mean particle size of up to 3 μm, said particles surface stabilized with one or more phospholipid surface modifiers, and a pharmaceutically acceptable amount of a water soluble polyhydroxy thermoprotecting agent, wherein (i) the ratio of said drug substance to said surface modifier is about 3:1 to about 5:1, (ii) the amount of said surface modifier is in the range from about 0.2% w/w to about 5.0% w/w, and (iii) said volume weighted mean particle size is not increased more than two-fold during and after terminal steam sterilization, and wherein said

composition is devoid of surfactants that require during terminal steam sterilization elevation of their cloud point temperature by addition of a cloud point modifier and is devoid of surfactant additives which coagulate on steam sterilization, and the ratio of the amount of the active substance and the thermoprotecting agent is selected to provide particle size stability during and after terminal steam sterilization.

23. (Previously Presented) The composition according to claim 21 or claim 22, wherein the suspension also includes a nonsurfactant additive to adjust osmotic pressure.

24. (Previously Presented) The composition according to claim 21 or claim 22, wherein the suspension is diluted with water for parenteral administration.

25. (Previously Presented) The composition according to claim 22, wherein the polyhydroxy compound is selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol, and mixtures thereof.

26. (Previously Presented) The composition according to claim 21 or claim 22, wherein the phospholipid surface modifier is selected from the group consisting of natural phospholipids and synthetic phospholipids.

27. (Previously Presented) The composition according to claim 26, wherein the natural phospholipid is an egg phospholipid or soy phospholipid.

28. (Previously Presented) The composition according to claim 22, wherein the suspension further comprises a pharmaceutical excipient for ophthalmic, peroral, or transdermal administration of the water insoluble or poorly soluble drug substance.

29. (Previously Presented) The composition according to claim 21, wherein the active substance is an antifungal agent.

30. (Previously Presented) The composition according to claim 29, wherein the antifungal agent is itraconazole.

31. (Previously Presented) The composition according to claim 21, wherein the active substance is an immunosuppressive agent.

32. (Previously Presented) The composition according to claim 21, wherein the active substance is a sterol.

33. (Previously Presented) The composition according to claim 32, wherein the sterol is alfaxalone.

34. (Previously Presented) A lyophilized or spray dried powder prepared from the composition according to claim 22.

35. (Previously Presented) The composition according to claim 22, wherein the water-insoluble or poorly water soluble drug substance is suitable for either immediate release or sustained release delivery of said drug substance by parenteral administration.

36. (Previously Presented) The composition according to claim 35, wherein the parenteral administration is intramuscular, intravenous, or subcutaneous administration.

37. (Previously Presented) The composition according to claim 31, wherein the immunosuppressive agent is a cyclosporin.

38. (Previously Presented) An aqueous suspension consisting essentially of (i) particles of a water insoluble or poorly soluble biologically active substance, (ii) from about 0.2 % w/w to about 5 % w/w of one or more phospholipid surface modifiers, and (iii) a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, sealed in a vial under nitrogen atmosphere, said suspension containing particles of the water insoluble or poorly soluble biologically active substance, said particles comprising a volume weighted mean particle size of up to 3 μm, with not more than 3000 particles of a size of 10 μm or greater and not more than 300 particles of a size of 25 μm or greater, wherein the ratio of the amount of the active substance to the phospholipid surface modifier and/or the thermoprotecting agent is selected so as to provide particle size stability during and after terminal steam sterilization, and wherein the volume weighted mean particle size subsequent to terminal steam sterilization is not more than

about two-fold of the volume weighted mean particle size prior to the terminal steam sterilization, and the suspension is devoid of surfactants which coagulate on steam sterilization.

39. (Canceled)

40. (Previously Presented) The suspension according to claim 38, wherein the pH of the suspension before terminal steam sterilization is from about 5 to about 9.

41. (Previously Presented) The suspension according to claim 38, further comprising a non-surfactant additive to adjust osmotic pressure of the suspension.

42. (Previously Presented) The suspension according to claim 38, further comprising an amount of a non-surfactant additive such that, on diluting the suspension with a pharmaceutically acceptable diluent suitable for parenteral administration to a pharmaceutically acceptable concentration for parenteral administration, a suitable osmotic pressure of the diluted suspension results.

43. (Previously Presented) The suspension according to claim 38, wherein the thermoprotecting agent is selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol, and mixtures thereof.

44. (Previously Presented) The suspension according to claim 38, wherein the one or more phospholipid surface modifiers are natural phospholipids or synthetic phospholipids.

45. (Previously Presented) The suspension according to claim 44, wherein the natural phospholipid is an egg phospholipid or soy phospholipid.

46. (Previously Presented) The suspension according to claim 38, wherein the amount of the surface modifier provides a biologically active substance to surface modifier ratio of 3:1 to 5:1.

47. (Canceled)

48. (Previously Presented) The suspension according to claim 38, further comprising a pharmaceutical excipient for ophthalmic, peroral, or transdermal administration of the water insoluble or poorly soluble biologically active substance.

49. (Previously Presented) The suspension according to claim 38, wherein the active substance is an antifungal agent.

50. (Previously Presented) The suspension according to claim 49, wherein the antifungal agent is itraconazole.

51. (Previously Presented) The suspension according to claim 38, wherein the active substance is an immunosuppressive drug.

52. (Previously Presented) The suspension according to claim 51, wherein the immunosuppressive drug is a cyclosporin.

53. (Previously Presented) The suspension according to claim 38, wherein the active substance is a sterol.

54. (Previously Presented) The suspension according to claim 53, wherein the sterol is alfaxalone.

55. (Canceled)

56. (Previously Presented) The suspension according to claim 38, wherein the water-insoluble or poorly water-soluble biologically active substance is at a pharmaceutically acceptable concentration for either immediate release or sustained release delivery of the active substance by parenteral administration.

57. (Previously Presented) The suspension according to claim 56, wherein the parenteral administration is intramuscular, intravenous, or subcutaneous administration.

58.-62. (Canceled)

63. (Previously Presented) The aqueous suspension according to claim 38, further wherein the suspension is substantially devoid of surfactants that require elevation of their cloud point temperature by addition of a cloud point modifier for further stabilization.